UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,362	10/30/2003	Edward W. Merrill	00952-8081	6751

90628 7590 07/18/2011

Massachusetts General Hospital
The General Hospital Corporation
Perkins Cole LLP
700 13th Street, NW, Suite 600
Washington, DC 20005-3960

EXAMINER	
BERMAN, SUSAN W	

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
07/18/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jisacson@perkinscoie.com
dmayhew@perkinscoie.com
patentprocurement@perkinscoie.com

Office Action Summary	Application No.	Applicant(s)	
	10/696,362	MERRILL ET AL.	
	Examiner	Art Unit	
	SUSAN W. BERMAN	1765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-14-11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2011 has been entered.

Response to Amendment

See the rejection of claims under 35 USC 112, first paragraph, herein below.

See the rejection of claims under 35 USC 112, second paragraph, herein below.

The rejection of claims 124-129 under 35 U.S.C. 102(b) as being anticipated by Dijkstra et al, in the article "Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Bean Irradiation" published May, 1989, is withdrawn. Applicant's argument that Dijkstra et al do not teach heating to a temperature within the instantly recited range is persuasive. However, it is noted that the claim recitation "about 230^0C to about 300^0C" is not supported by the specification as originally filed.

The rejection of claims 127-129 under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626) is maintained.

Claims 124-126 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626).

Claims 124-129 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900).

Response to Arguments

Applicant's arguments filed 06-14-2010 have been fully considered but they are not persuasive. See the previous discussions of these issues in the Office Actions mailed 1/14/2007, 09-07-2007, 12-12-2006, 07-24-2008. 09-14-2009 and 03-15-2010.

Dijkstra et al: Applicant argues that Dijkstra et al disclose a process for making bar stocks and not a process for making an orthopaedic implant. This argument is unpersuasive because the phrase "for preparing an orthopaedic implant prosthesis bearing having improved mechanical properties and increased wear resistance" is merely a statement of intended use and is not sufficient to distinguish over prior art references that disclose the same process steps as set forth in the instant claims for the intended purpose. Sine the process steps claimed and the process steps disclosed in the prior art are the same, the prior art process is considered to be sufficient for the intended purpose set forth in the instant claims.

Applicant's arguments with respect to what is inherent to the disclosure, such as a method of heating and irradiation that comprises heating before irradiation and irradiation before heating being inherently disclosed because the use of a van der Graaff generator is disclosed and one skilled in the art would recognize that repetitions of the recited steps are necessary to obtain a desired radiation dose, are not considered to be relevant to the instant claims. The arguments are not persuasive because repetitions of the recited steps are not set forth or required in the instant claims. There is no issue of patentability to which these arguments are relevant.

With respect to whether Hyon et al is prior art, applicant continues to argue that the Declaration of Merrill et al filed 06-08-2009 evidences reduction to practice of a method wherein UHMWPE is irradiated and subsequently melted before January 20, 1995. However, there are no

examples in the Exhibits supplied with the Declaration evidencing a process wherein UHMWPE is irradiated before melting. The argument that the use of a van der Graaff generator evidences a process of irradiating followed by melting ignores that the disclosed process evidenced in the Declaration starts with melting the UHMWPE sample, not with irradiation. Furthermore, the Declaration in section 10 states that Cold-irradiation and Subsequent Melting is disclosed in US Serial No. 08/726,313 filed 10-02-1996. The statement "b", i.e., "crosslink as solid, melt, recrystallize" under "Basic Motivation" in Exhibit 1 is a statement of intent to explore but not evidence of a reduction to practice. Applicant's argument that Hyon et al is not prior art is unpersuasive for reasons of record. Applicant argues that the examiner has not properly construed the Declarations of record. The Declarations of record have been previously discussed and the examiner's conclusions are already of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner has not found any description of a process comprising heating an UHMWPE preform to a temperature "of about 230^0C to about 300^0C". Applicant discloses

heating at a temperature "of about 137^{0}C to about 300^{0}C, more preferably about 140^{0}C to about 300^{0}C, more preferably yet about 140^{0}C to about 190^{0}C, more preferably yet about 145^{0}C to about 190^{0}C, and most preferably about 150^{0}C" in paragraph [0058] of PrePub 2004/0132856. A temperature "of about 230^{0}C" is not mentioned. None of the Examples discloses a temperature of about 230^{0}C.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "subsequently irradiating the preform" does not clearly set forth what is intended by "subsequently". Does applicant intend step c to be subsequent to step a or subsequent to step b? The claim language should clearly set forth whether irradiating the preform takes place after providing the preform or after heating the preform. The claim recitation should also be clearly differentiated from the recitations in claim 127, which do not specify the order of irradiating and heating, to avoid duplication. It is noted that claims 124 and 127, as written, claim the same process.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that instant claims 124-126, considered wherein the preform is irradiated subsequent to heating are entitled to the 02-13-1996 filing date of US 5,879,400 because this

parent patent discloses the method of melt irradiation (MIR). Instant claims 124-126, considered wherein the preform is irradiated subsequent to providing and before heating, encompasses the WIR-SM and CIR-SM processes disclosed in SN 08/726,313, having an effective filing date of 10-02-1996. The instant claim language in 127-129 sets forth the IR-SM processes first disclosed in SN 08/726,313, but not disclosed in US '400, and also encompasses the MIR process disclosed in US '400. Therefore, the effective filing date for instant claims 127-129 is considered to be 10-02-1996, the filing date of application SN 08/726,313, which discloses WIR-SM and CIR-SM methods as well as the "MIR" method.

Claims 124-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of May 06, 1996). Hyon et al disclose a method for producing UHMWPE for an artificial joint comprising irradiating UHMWPE with a low dose of radiation followed by compression-deformation after melting at a high temperature around the melting point and then cooling and solidifying. Hyon et al teach a process employing a temperature from the melting point minus 50^0C to the melting point plus 80^0C, which teaches temperatures within the range of 230^0C to 300^0C set forth in the claims. Table 2 appears to show that the samples treated according to the disclosed process have an increased tensile strength and an increased Young's modulus. With respect to claims 125 and 128, Hyon et al disclose temperatures around or not less than the melting point, preferably 160-220 ^{0}C, that suggest the instantly recited temperature "about 230^0C" (column 4, lines 4-16). Claims 125 and 128 are anticipated by the teaching of With respect to claims 126 and 129, Hyon et al teach a preferable dose 0.01 to 5.0 MR (column 3, lines 62-65). Thus the process disclosed by Hyon et al

anticipates the process of instant claims 126 and 129 wherein the gamma radiation dose is about 1 Mrad to 5.0 Mrad.

Claims 124-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of July 09, 1996). Shen et al disclose a process comprising irradiating preformed UHMWPE and remelting the irradiated UHMWPE in order to enhance the wear-resistance of polymers and in vivo implants obtained from the polymers (column 4, lines 8-18, and lines 46-51, and column 6, lines 43-49). Shen discloses radiation doses from about 1 to about 100 Mrad (column 7, lines 20-31). The irradiated polymer is remelted at a temperature from about 100^0C to about 160^0C above the melting temperature of the irradiated polymer, preferably from about 136^0C to about 300^0C (column 7, line 53, to column 8, line 3). Thus, Shen et al disclose the instantly claimed process wherein preformed UHMWPE is irradiated at a dose of at least 1 Mrad and remelted at a temperature of about 230^0C to about 300^0C within the disclosed temperature range from about 136^0C to about 300^0C.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129, 131-134 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point to about 300^0C and the time period is from about 5 minutes to about 3 hours or a time period of 5 minutes to about 24 hours and the polyethylene is UHMWPE. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. Thus the limitations of the process set forth in the instant claims are obvious variants of the limitations set forth in the claims of A.N. 10/197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-125, 130 and 143-146 of copending parent Application No. 09/764,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. The polyethylene recited in the claims of A.N '445 encompasses the UHMWPE recited in the instant claims. Claims 124, 125 and 130 suggest

instant claim 127. Claim 143 suggests instant claim 124. Thus species within the instant claims are obvious from the limitations set forth in the claims of A.N. 09/764,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN W. BERMAN whose telephone number is (571)272-1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
7/7/2011

/SUSAN W BERMAN/
Primary Examiner, Art Unit 1765